



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1537]

James R. Casey: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring James R. Casey for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Casey was convicted, as defined in the FD&C Act, of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Casey was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of June 30, 2019 (thirty days after receipt of the notice), Mr. Casey had not responded. Mr. Casey's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa (ELEM-4029) Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857 or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act (21 U.S.C. 335a(b)(3)(A)), that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On January 9, 2019, Mr. Casey was convicted as defined in section 306(l)(1)(B) of the FD&C Act, in the United States District Court for the Eastern District of Virginia, when the court accepted his plea of guilty and entered judgment against him for the offense of conspiracy to violate the Lacey Act in violation of 18 U.S.C. 371 and 16 U.S.C. 3372(d) and 3373(d)(3)(A)(ii).

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the Stipulation of Facts incorporated into Mr. Casey's Plea Agreement, filed on September 26, 2018, from on or

about 2010 to June 2015, while serving as the owner, operator, and President of Casey's Seafood, Inc. ("the company"), Mr. Casey regularly purchased foreign crab meat from a variety of sources and from a number of different countries. Mr. Casey also purchased foreign crab meat that had been recalled, returned, or that was approaching or beyond its posted "best used by" dates. Mr. Casey directed company employees to unpack the foreign crab meat from containers and re-pack the crab meat into company containers, all of which were labeled "Product of USA." During that time period, employees routinely emptied foreign crab meat onto tables, comingling crab meat from different sources, and then re-packaged the crab meat into company containers, all of which were labeled "Product of USA." From on or about July 1, 2012 and continuing until June 17, 2015, Mr. Casey caused to be sold at least 367, 765 pounds of crab meat falsely labeled "Product of USA" with a total wholesale value of approximately \$4, 324, 916.

As a result of this conviction, FDA sent Mr. Casey by certified mail on May 22, 2019, a notice proposing to debar him a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) that Mr. Casey's felony conviction of conspiracy to violate the Lacey Act in violation of 18 U.S.C. 371 and 16 U.S.C. 3372(d) and 3373(d)(3)(A)(ii) constitutes conduct relating to the importation into the United States of an article of food because the offense he committed involved falsely labeling crab meat that was imported from a number of foreign countries as "Product of USA."

The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Casey should be subject to a 5-year period of debarment. The proposal also offered Mr. Casey an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and

advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Casey failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Casey has been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Casey is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Mr. Casey is a prohibited act.

Any application by Mr. Casey for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2019-N-1537 and sent to the Dockets Management Staff (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket, and will be viewable at <http://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-25848 Filed: 11/27/2019 8:45 am; Publication Date: 11/29/2019]